

**REMARKS**

The present application was filed on September 27, 2001 having claims 1-27. Claims 1-23 having now been cancelled, claims 24-27 remain pending in the application. The non-elected claims and claims 20-23 have been cancelled, and the word "whereby" in claim 24 has been amended to "wherein" in order to place this case in better condition for appeal, in case an appeal becomes necessary.

In the Office Action dated November 6, 2003, the Examiner: (1) repeated the rejection of claim 24 under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 4,959,068 to Bendel et al.; (2) rejected claim 20 under 35 U.S.C. §103(a) as obvious over Bendel et al. in view of U.S. Patent No. 5,458,616 to Granger et al.; and (3) rejected claims 22, 23, and 26-27 under 35 U.S.C. §103(a) as obvious over U.S. Patent No. Patent No. 5,458,616 to Granger et al. (or U.S. Patent No. 5,258,013 to Granger et al.) in view of U.S. Patent No. 6,025,025 to Bartrug et al.<sup>1</sup> Reconsideration of the foregoing rejections is respectfully requested.

With respect to the rejection of claim 24 under 35 U.S.C. §102(b) in view of Bendel et al., the Examiner asserts the reference discloses each of the limitations in the recited claim and that the function in the whereby clause is capable of being performed by Bendel et al. since there is no "structure difference between the claim and the reference."

However, nowhere does Bendel et al. disclose or suggest the functional limitation recited in claim 24, namely, that its needles having "a penetration force on a fifth pass through a microporous polyurethane member of about 0.042 inches thickness that is at least 10% less than the penetration force on a fifth pass through a microporous polyurethane member of about 0.042 inches thickness of a needle having the same silicone-containing coating on the same surgical needle having no surface that is acid treated." This is not surprising, because Bendel et al. is simply not concerned with improving penetration forces by pre-treating a needle.

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<sup>1</sup> The prior rejection of Claims 22 and 24 under 35 U.S.C. §112, second paragraph as being indefinite has not been repeated; applicants' respectfully submit this rejection was overcome in applicants' prior amendment of August 20, 2003.

To the contrary, the purpose of the acid treatment in Bendel et al. is not to improve penetration force, but rather to blacken the needle to form a dark, non-reflective, non-flaking surface having improved visibility in the surgical field. While the examples of Bendel et al. report penetration characteristics, there is clearly no appreciation that an acid pre-treatment provides any improvement in penetration force after five passes through a material. Based on the specific and severe reaction conditions required to achieve the blackening, there is no reasonable basis for one skilled in the art to derive any relevant teaching or suggestion from Bendel regarding an improvement in penetration force. Bendel requires a strong acid (sulfuric is the only acid mentioned), the presence of a dichromate (which one skilled in the art reading Bendel has no basis to expect any improvement in penetration force) and temperature in excess of 100 °C. (Bendel states that this is important to obtain the blackening at column 3, lines 30-32). Only this combination of conditions is described to provide Bendel's specific blackening effect. If it is the examiner's position that Bendel provides any suggestion that in addition to blackening Bendel's process improves penetration force compared to a needle that has not undergone acid treatment, the Examiner is respectfully requested to specifically point out (i.e., by column and line) where in Bendel such suggestion or motivation can be found.

In view of the vastly different purpose of the Bendel et al. treatment, it is not surprising that Bendel et al. does not disclose that its acid treatment results in reduced penetration forces after multiple passes through a microporous polyurethane member of about 0.042 inches thickness. Bendel et al. is merely concerned with improving visibility of the needle. Bendel et al. does not address improving penetration force or even appreciate that maintaining good penetration force after multiple passes through tissue is a concern. Accordingly, independent claim 24, which must be read to include its functional limitation (*see* MPEP 2173.05(g)), is believed to be patentably distinct from the Bendel et al. patent. Therefore, in view of the above remarks, reconsideration of this rejection is respectfully requested.

The rejections of Claims 20, 22 and 23 are now moot.

Claims 26-27 were rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. Patent No. 5,458,616 to Granger et al. (or U.S. Patent No. 5,258,013 to Granger et al.) in view of U.S. Patent No. 6,025,025 to Bartrug et al.

Bartrug et al. fails to disclose anything about surgical needles. Thus Bartrug et al. fails to disclose acid treatment of a surgical needle surface. Bartrug et al. also fails to disclose improving needle penetration forces after five passes through tissue.

It is not surprising that Bartrug et al. discloses nothing with respect to surgical needle penetration forces since Bartrug et al. is directed to methods for improving the adherence of water-repellent films on the surface of a substrate. While Bartrug et al. discloses a wide variety of substrates which may be coated, only glass substrates are exemplified. Bartrug et al. does not disclose treating needles, and there is nothing in Bartrug et al. to suggest its compositions may be utilized to improve the lubricity of surgical needles.

In fact, it would be virtually impossible to apply the Bartrug process to a surgical needle. The Bartrug process requires that the abrasive compound be wiped onto the substrate with applied pressure. Bartrug not only states that the amount of pressure to be applied is a factor when choosing the abrasive (see Bartrug at column 5, lines 25-29: "...the amount of force directed toward the substrate and the number of passes to be applied over the surface of the substrate should be considered when selecting an abrasive compound."), but also indicates that an *orbital sander* can be used to apply the abrasive.

"For example, the dispersion may be applied directly on the substrate surface and wiped by hand, applying moderate hand pressure to an absorbent, acid-resistant pad. The dispersion may also be applied directly to the pad and subsequently wiped on the substrate surface. Alternatively, powered equipment *such as an orbital sander* with a non-abrasive pad may be used to apply the abrading compound/acid solution dispersion."  
(Bartrug at column 6, lines 2-9. Emphasis added.)

Thus, as a practical matter, the Bartrug process cannot reasonably be applied to surgical needles. The mention of an orbital sander shows just how irrelevant to the treatment of surgical needles.

Moreover, Bartrug et al. teaches away from Applicants' acid treatment.

According to Bartrug et al. at Col. 3, Lines 11-24,

The abrading compound/acid solution dispersion loosens and dislodges materials, such as surface contaminants and other glass constituents, which block the bonding sites, without materially affecting the mechanical or optical properties of the surface of the substrate. A synergistic effect has been observed where the abrading compound is dispersed in the acid solution. More particularly, a water-repellent film applied to a substrate surface prepared with the abrading compound/acid solution dispersion generally exhibits improved durability as compared to preparing the substrate surface with an abrading operation alone or an acid washing operation alone, and at least as good or better than an abrading operation followed [sic] a separate acid washing operation.

One reviewing Bartrug et al.'s abrading compound/acid solution dispersion to obtain enhanced water-repellency for glass would in no way be motivated to attempt such a treatment on a surgical needle to obtain enhanced lubricity. In fact, the abrasive compound of Bartrug et al. may very well degrade the needles to an extent rendering them unfit for medical use. In addition, the synergy of abrading compound and acid solution as described by Bartrug et al. would suggest to one skilled in the art that an acid treatment alone is insufficient to obtain a water-repellent coating and similarly would be insufficient for the treatment of needles as disclosed by applicants. Thus, contrary to the Examiner's assertions, it is respectfully submitted that one skilled in the art would not, in fact, look to Bartrug et al. for coating metal needles with silicone, nor would one skilled in the art look to Bartrug et al. for coating metal needles without Bartrug et al.'s abrading operation.

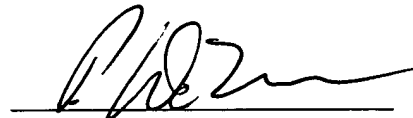
As noted above, Granger et al. discloses a needle that is coated with silicone. However, there is simply no suggestion or motivation to combine Bartrug et al. and Granger et al. in the manner suggested in the Office Action.

One skilled in the art faced with the problem of improving needle penetration force would not, in the first instance, look to Bartrug et al.'s abrading compound/acid solution for enhanced water repellency, especially since glass is the only substrate

exemplified by Bartrug et al. Nor would one skilled in the art have any motivation to combine Bartrug et al.'s teachings with respect to water repellency on glass with Granger et al.'s silicone-coated needle. Without such suggestion or motivation, independent Claims 20 and 24 are non-obvious over Bartrug et al. and Granger et al. whether taken alone or in any combination. Claims 22-23 and 26-27, which depend from Claims 20 and 24 respectively, are thus non-obvious over the references as they incorporate all of the limitations of their dependent base claims.

It is believed that the claims of the application, i.e., claims 24-27, are patentably distinct over the art of record and are in condition for allowance. In the event that the examiner believes that a telephone conference or a personal interview may facilitate resolution of any remaining matters, the undersigned may be contacted at the number indicated below. In view of the foregoing amendment and remarks, early and favorable action on this application are earnestly solicited.

Respectfully submitted,



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